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William Cork

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

FORMAN, BETTY J

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,780

Applicant(s)

CORK ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, Claims 15-25 in the reply filed on 26 July 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-25 are indefinite in Claim 15 because the claim is drawn to a method for detecting the presence of targets in a test spot. The claim defines the test spots as follows: "a test spot for metallic nanoparticles complexed thereto in the presence of one or more target analytes". This recitation defines an intended use for the test spot i.e. for complexing in the presence of target". The claim further recites method steps of illuminating the substrate, acquiring images of the test spots, and determining the presence of complexes. However, because the method does not contain steps of adding a target analyte, it is unclear how or whether the presence of complexes can be determined. Therefore, it is unclear whether the method steps accomplish the stated goal.

Claim 16 is indefinite because it defines the control spot. However, Claim 15 defines the substrate as having "a control spot or a second test spot". As written, Claim 15 does not require the presence of a control spot. Therefore, Claim 16 lacks proper antecedent basis in Claim 15 because it does not further limit the non-control spot embodiment encompassed by Claim 15.

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Claim 17 is indefinite for the recitation "the comparison sample" because the recitation lacks proper antecedent basis in Claim 15, which does not have a comparison sample or comparison step. The claim is further indefinite because it does not further define the elements used in the method of Claim 15.

Claim 18 is indefinite in lines 3-4 for the recitation "determining an optimal exposure time for the well" because the "well" lacks proper antecedent basis in the "plurality of wells" of line 1.

Claims 20-25 are indefinite in Claim 20, line 2 for the recitation "in the spot containing the test sample" because the recitation lacks proper antecedent basis in Claim 15 which does not define a spot as having a test sample.

Claims 20-25 are indefinite in Claim 20, line 4 for the recitation "the test and comparison spots" because the recitation lacks proper antecedent basis in Claim 15 which does not define a comparison spot. It is further noted that each of Claims 20-25 are indefinite for the recitation "the comparison spot"

Claims 20-25 are indefinite in Claim 20, line 7 for the recitation "for the test and control spot" because the recitation lacks proper antecedent basis in Claim 15 which does not define the substrate as having a control spot. , Claim 15 defines the substrate as having "a control spot or a second test spot". As written, Claim 15 does not require the presence of a control spot. Therefore, Claims 20-25 lack proper antecedent basis in Claim 15 because Claim 20 does not further limit the non-control spot embodiment encompassed by Claim 15.

Claims 20-25 are indefinite in Claim 20, line 9 for the recitation "the test containing the test sample" because the recitation lacks proper antecedent basis in Claim 15 which does not define the test spot as having a test sample.

Claim 23 is further indefinite for the recitation "the functions generated" because the recitation lacks proper antecedent basis in the claims. The claims from which Claim 23 depend do not define generated functions.

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Claim 24 is further indefinite because the claim defines a step of comparing intensities of the test and control spots by performing statistical analysis on the intensities of the comparison and test spots. Claim 24 depends from Claim 23, which defines a step of determining intensities for test and comparison spots. Hence, Claim 24 is indefinite because it is unclear whether the intensities being compared are those obtained in Claim 23.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Stimpson et al (U.S. Patent No. 5,599,668, issued 4 February 1997).

Regarding Claim 15, Stimpson et al disclose a method for detecting the presence of a target, the method comprising illuminating the light-receiving edge of a substrate to create total internal reflection, acquiring multiple images of the test spot and control/second spot (e.g. second situs, Column 11, line 33-Column 12, line 62), the multiple images taken at different exposures (i.e. different exposure times) and determining the presence of metallic nonoparticles (i.e. LSL, Column 16, lines 25-33) to determine presence of targets (Column 5, line 15-Column 6, line 42).

Regarding Claim 16, Stimpson et al teach the method wherein the substrate comprises multiple sites including positive, negative, calibration controls (Column 12, lines 28-31). However, as stated above, it is noted that the claim does not further limit the non-control embodiment of Claim 15. Furthermore, it is noted that Stimpson et al teach the method

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wherein controls are provided by selenium anti-biotin conjugate complexing with analyte at a known location of the substrate (Examples 4-6).

Regarding Claim 17, Stimpson et al teach the method wherein the test sample comprises a wildtype nucleic acid and the comparison comprises a mutant (i.e. single mismatch, Example 4-5). It is noted that Claim 15 does not require a sample and as such, the limitation defining the sample do not further limit the method of Claim 15.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al (WO 97/35181, published 25 September 1997) in view of Stimpson et al (U.S. Patent No. 5,599,668, issued 4 February 1997).

Regarding Claim 15, Herron et al disclose a method for detecting the presence of a target, the method comprising illuminating the light-receiving edge of a substrate to create total internal reflection, acquiring multiple images of the test spot and control/second spot (e.g. well patches comprising measurement well (152) and calibration well (154), page 14, line 31-page 15, line 25), acquiring multiple images taken at different exposures (pages 21-25) and determining the presence of target analyte complexes (page 23, line 24-page line 25, Fig. 3-4, 10-11). Herron et al teach the analyte complexes are labeled with tracer molecules (page 13, lines 24), but they do not specifically teach the labels are metallic nanoparticles. However, metallic nanoparticle labels were well known and routinely practiced in the art at the time the claimed invention was made as taught by Stimpson et al.

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Stimpson et al disclose a similar method for detecting the presence of a target, the method comprising illuminating the light-receiving edge of a substrate to create total internal reflection, acquiring multiple images of the test spot and control/second spot (e.g. second situs, Column 11, line 33-Column 12, line 62), the multiple images taken at different exposures (i.e. different exposure times) and determining the presence of metallic nonoparticles (i.e. LSL, Column 16, lines 25-33) to determine presence of targets (Column 5, line 15-Column 6, line 42). Stimpson et al further teach the light scattering labels allows for precise detection of signal within a confined area thereby permitting simultaneous interrogation of the entire array and/or real-time measurement of binding and/or melting (Column 3, lines 45-55). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the light-scattering metallic labels of Stimpson et al to the method of Herron et al. One of ordinary skill in the art would have been motivated to do so for the expected benefits taught by Stimpson i.e. the light scattering labels allows for precise detection of signal within a confined area thereby permitting simultaneous interrogation of the entire array and/or real-time measurement of binding and/or melting (Column 3, lines 45-55).

Regarding Claim 16, Herron et al teach the method wherein the control/second spot comprises a label conjugated to the substrate via a nucleic acid (page 13, lines 9-24, page 14, lines 7-10). Stimpson et al also teach the method wherein the substrate comprises multiple sites including positive, negative, calibration controls (Column 12, lines 28-31).

Regarding Claim 17, Herron et al teach the method wherein the analyte and capture probes are nucleic acids (page 14, lines 7-10). Stimpson et al teach the similar method wherein the test sample comprises a wildtype nucleic acid and the comparison comprises a mutant (i.e. single mismatch, Example 4-5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the wildtype/mutant nucleic acids of Stimpson to the method of Herron. One of ordinary skill in the art would have been motivated to do so based on the well known clinical importance of mutations.

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Regarding Claim 18, Herron et al teach the method wherein the substrate comprises a plurality of wells containing test and comparison spots (Fig. 3, page 14, line 31-page 15, line 25) and further determining an optimal exposure (page 22, lines 3-17), wherein the images are taken at an optimal exposure time and at least one that is less than optimal (page 23, line 24-page 24, line 25).

Regarding Claim 19, Herron et al teach the method wherein determining optimal exposure includes determining saturation (page 22, lines 3-17).

Regarding Claim 20, Herron et al teach the method further comprising performing regression analysis of test spots (I vs T, Fig. 10-11), selecting optimal exposure time, determining intensity for optimal exposure and determining presence of analyte by comparing intensity of test spot with intensity of control spot (page 23-26).

Regarding Claim 21, Herron et al teach the method wherein the signal processing uses analog detectors and analog-digital converters (page 20, lines 24-32) but they are silent regarding pixel values. However, Stimpson et al teach the similar method wherein the analog-to-digital conversion assigns a numerical value to each pixel (Column 22, lines 5-19). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the pixel values known in the art as taught by Stimpson to the analog-digital conversion of Herron et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the well known practice of doing so as taught by Stimpson (Column 22, lines 5-19).

Regarding Claim 22, Herron et al teach the method wherein selecting an optimal exposure comprises determines saturation (page 22, lines 3-17).

Regarding Claim 23, Herron et al teach the method wherein the step of determining intensity comprises extrapolation from generated signals (e.g. low control sample and high control sample, (page 23, lines 15-23). Stimpson et al teach the similar method wherein the data is interpolated (Example 2, Column 24, lines 35-53).

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Regarding Claim 24, Herron et al teach the method wherein comparing intensity of the test spot includes performing statistical analysis to determine similarity to the control spot (page 23, line 15-page 24, line 25). Stimpson et al teach the similar method wherein the intensity is analyzed statistically (e.g. Example 2, Column 24, lines 35-53 and Example 5, Column 20, lines 46-58).

Regarding Claim 25, Herron et al teach the method wherein comparing intensity of the test spot includes performing statistical analysis to determine similarity to the control spot (page 23, line 15-page 24, line 25) but does not specifically teach means testing. However, Stimpson et al teach the similar method wherein the statistical analysis included means testing (Example 2, Column 24, lines 35-53 and Example 5, Column 20, lines 46-58).

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 15-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 51-67 of copending Application No. 11/530,110 (U.S. Patent Application Publication No. 2007/0041624).

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double

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patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 15-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51 and 66 of U.S. Patent No. 11/530,138 (U.S. Patent Application Publication No. 2007/0148665). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting spots on the substrate wherein the spots comprising metallic nanoparticles. The claim sets merely differ in that the '138 claims define an additional step of compensating for distortion. However, the open claim language "comprising" as recited in the instant claims encompass the additional step of compensation recited in the '138 claims. Therefore, the claim sets are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 18, 2007